

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

MYERS BIGEL SIBLEY SAJOVEC, P.A.
P.O. Box 37428
Raleigh, NC 27627
UNITED STATES OF AMERICA

06-23-05 A09:00 IN

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference

9336.20.WO

Date of mailing
(day/month/year)

22/06/2005

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2004/035424

International filing date
(day/month/year)

26/10/2004

Applicant

ORIEL THERAPEUTICS, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Sylvie Fernandez

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 9336.20.WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2004/035424	International filing date (day/month/year) 26/10/2004	(Earliest) Priority Date (day/month/year) 27/10/2003
Applicant ORIEL THERAPEUTICS, INC.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☒ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

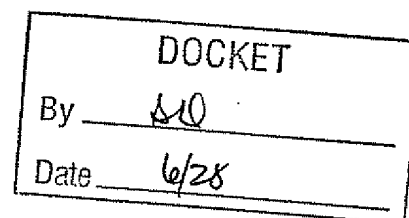
2. ☐ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

**5. With regard to the abstract,**

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 4A

☐ as suggested by the applicant.

☒ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2004/035424

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Dry powder drug containment packages (25) with tab members (30) and metered dose sealed drug compartments (25d) can be used in an inhaler (10) having a flow chamber (40) with a hook member (50) that opens the drug compartments (25d) and/or a portion that flexes to vibrate the dry powder to facilitate fluidic active dispersion for inhalation.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/035424

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1,2,4,5,7,9,12-17,25

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 2, 4, 5, 7, 9, 12-17, 25

None

2. claims: 3, 4, 6, 8, 21

A drug containment system wherein the tab members have a loop member

(Problem: to avoid parts of the sealant material to be inhaled by the patient)

3. claims: 10, 11, 18

A drug containment system wherein each tab is associated with a plurality of drug compartments

(Problem: to allow combination inhalation dry powder drug delivery in operative position in an inhaler)

4. claims: 19, 20, 22-24

A drug containment system wherein the plurality of drug compartments is at least 60

(Problem: to permit the user to have a longer journey with only one package)

5. claims: 26-50, 65-74

A dry powder inhaler with vibrator, and method of operating
(Problem: to prevent agglomeration of the powder)

6. claims: 51-64

A multi-dose dry powder inhaler with a hook member
(Problem: to facilitate the opening of the blister)

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/035424

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61J1/03 A61M15/00 B65D75/36 B65B5/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J B65D A61M B65B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 622 166 A (EISELE ET AL) 22 April 1997 (1997-04-22) column 2, line 55 - column 3, line 42; figures 1-7 -----	1,2,4,5, 7,9, --- 12-17,25

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

11 March 2005

Date of mailing of the international search report

22 JUN 2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer

Zeinstra, H

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/035424

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5622166	A	22-04-1997	US 6328034 B1 11-12-2001
		AT 258450 T 15-02-2004	
		AU 695051 B2 06-08-1998	
		AU 5251096 A 18-11-1996	
		BG 62921 B1 30-11-2000	
		BG 101992 A 31-07-1998	
		BR 9608194 A 21-07-1998	
		CA 2217672 A1 31-10-1996	
		CN 1181709 A 13-05-1998	
		CZ 9703349 A3 14-01-1998	
		DE 69631419 D1 04-03-2004	
		DE 69631419 T2 11-11-2004	
		EP 0835147 A1 15-04-1998	
		HU 9801656 A2 28-10-1998	
		IL 117706 A 30-11-1999	
		JP 3574662 B2 06-10-2004	
		JP 10512788 T 08-12-1998	
		NO 974910 A 24-10-1997	
		NZ 304654 A 28-01-1999	
		PL 322909 A1 02-03-1998	
		RO 115407 B1 28-02-2000	
		RU 2162717 C2 10-02-2001	
		SK 144697 A3 04-03-1998	
		TW 384225 B 11-03-2000	
		US 2002040713 A1 11-04-2002	
		WO 9633759 A1 31-10-1996	
		US 5921237 A 13-07-1999	
		US 6029663 A 29-02-2000	
		AU 729272 B2 01-02-2001	
		AU 3646697 A 10-02-1998	
		BR 9710880 A 17-08-1999	
		CZ 9900189 A3 12-05-1999	
		EP 0925084 A1 30-06-1999	
		HU 9903819 A2 28-03-2000	
		JP 2001507949 T 19-06-2001	
		NO 990272 A 22-03-1999	
		NZ 333685 A 29-09-2000	
		NZ 505722 A 30-03-2001	
		WO 9803217 A1 29-01-1998	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220 . .

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCTUS2004/035424

International filing date (day/month/year)
26.10.2004

Priority date (day/month/year)
27.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61J1/03, A61M15/00, B65D75/36, B65B5/10

Applicant
ORIEL THERAPEUTICS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

DOCKET

By JO

Date 6/28

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Authorized Officer

Zeinstra, H

Telephone No. +31 70 340-2824



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/035424

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

International application No.
PCT/US2004/035424

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- because:

- Form PCT/ISA/237 (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/035424

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1, 2, 4, 5, 7, 9, 12-17, 25

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1,2,4,5,7,9,12-17,25
Inventive step (IS)	Yes: Claims	
	No: Claims	1,2,4,5,7,9,12-17,25
Industrial applicability (IA)	Yes: Claims	1,2,4,5,7,9,12-17,25
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/035424

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item IV.

1 The separate inventions/groups of inventions are:

1, 2, 4, 5, 7, 9, 12-17, 25:

None

3, 4, 6, 8, 21:

A drug containment system wherein the tab members have a loop member (Problem: to avoid parts of the sealant material to be inhaled by the patient)

10, 11, 18

A drug containment system wherein each tab is associated with a plurality of drug compartments

(Problem: to allow combination inhalation dry powder drug delivery in operative position in an inhaler)

19, 20, 22-24

A drug containment system wherein the plurality of drug compartments is at least 60 (Problem: to permit the user to have a longer journey with only one package)

26-50, 65-74

A dry powder inhaler with vibrator, and method of operating (Problem: to prevent agglomeration of the powder)

51-64

A multi-dose dry powder inhaler with a hook member (Problem: to facilitate the opening of the blister)

2 They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

2.1 The document US-A-5622166 (of which the document US-A-6029663 cited in the description is a continuation) cited in the search report discloses a dry powder inhaler

delivery system comprising essentially:

- a multi-dose package,
- a support member,
- a drug compartment,
- a sealant material,
- a tab member,
- an elongate chamber,
- an air inlet port,
- a mouthpiece.

Over this prior art, no special technical feature (in the meaning of Rule 13.2 PCT) remains in claims 1, 2, 4, 5, 7, 9, 12-17, 25 of the application.

2.2 Over this prior art, the potential special technical features (in the meaning of Rule 13.2 of the PCT) in the independent and dependent claims are:

Claims 1, 2, 4, 5, 7, 9, 12-17, 25: none,

Claims 3, 4, 6, 8, 21: A drug containment system wherein the tab members have a loop member,

Claims 10, 11, 18: A drug containment system wherein each tab is associated with a plurality of drug compartments,

Claims 19, 20, 22-24: A drug containment system wherein the plurality of drug compartments is at least 60,

Claims 26-50, 65-74: A dry powder inhaler with vibrator, and method of operating,

Claims 51-64: A multi-dose dry powder inhaler with a hook member.

2.3 Accordingly, it appears that a posteriori, the above listed claims do not satisfy the requirement of unity of invention.

2.4 Furthermore, it is pointed out that also when considering the effects associated with the different groups of claims, no single general inventive concept exists between said different groups. Since there exists no other common special technical feature within the meaning of Rule 13.2 PCT, no technical relationship between the different groups of claims can be seen.

Re Item V.

3 Reference is made to the following document:

D1 : US 5 622 166 A (EISELE ET AL) 22 April 1997 (1997-04-22)

4 INDEPENDENT CLAIM 1

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 (see column 2, line 55 - column 3, line 42, figures 1-7) discloses (the references in parentheses applying to this document):

A multi-dose drug containment system package adapted for use in an inhaler (20), comprising:

a support member (46) comprising a plurality of spaced apart drug compartments (36), each drug compartment (36) having a sealant material (56) detachably sealed thereto; and

a plurality of spaced apart tab members (48), a respective tab member (48) attached to a portion of sealant material (56) that extends over one or more drug compartments (36), wherein a respective tab member (48) is operatively associated with at least one drug compartment (36) so that, in operation, the respective tab member (48) is configured to be grasped, such grasping causing the associated sealant material (56) to pull away from at least one drug compartment (48) to release a drug held therein.

5 DEPENDENT CLAIMS 2, 4, 5, 7, 9, 12-17, 25

Dependent claims 2, 4, 5, 7, 9, 12-17, 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT).

- 5.1 In particular, the features of claims 2, 4, 5, 7, 9, 12-17, 25 are disclosed in combination with the features of claim 1 in D1 (see column 2, line 55 - column 3, line 42, figures 1-7).
- 6 The system package described in the claims is industrially manufacturable, and therefore meet the requirements of Article 33(4) PCT.

Re Item VII.

- 7 Independent claims 1, 15 and 16 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 8 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 9 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.